Supplemental Amendment
Applicants: Rudy Mazzocchi et al.
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AMENDMENTS TO THE SPECIFICATION:

Replace the paragraph beginning on page 3, line 20, and ending on page 3, line 28, with:

Accordingly, it would be desirable to provide a method for forming devices for deployment ~~in a vessel~~ in a patient's vessel which is both economical and yields consistent, reproducible results. It would also be advantageous to provide a reliable embolization device which is both easy to deploy and can be accurately placed in a vessel. Furthermore, there is a need in the art for a trap or filter which can be deployed within a vessel for capturing thrombi, which trap can be reliably deployed; if the trap is to be used only temporarily, it should be readily withdrawn from the patient without simply dumping the trapped thrombi back into the blood stream.

Replace the paragraph beginning on page 6, line 10, and ending on page 6, line 11, with:

Figure 11B is a schematic side view of the medical device of Figure ~~11A~~ 11A in an expanded state for deployment in a patient's vascular system;

Replace the paragraph beginning on page 26, line 22, and ending on page 27, line 4, with:

In the embodiment illustrated in Figures 9, though, the ends of the wire strands adjacent the forward end 184 in the finished device need not be affixed to one another in any fashion. These strands are held in a fixed position during the forming process to prevent the metal fabric from unraveling before it is made into a finished device. While the ends of the wire strands adjacent the forward end remain fixed relative to one another, they can be heat treated, as

outlined above. The heat treatment will tend to fix the shapes of the wires in their deformed configuration wherein the device generally conforms to a molding surface of the molding element. When the device is removed from contact with the molding element, the wires will retain their shape and tend to remain intertwined. Accordingly, when the device is released from contact with the molding element, even if the ends of the wires are released from any constraint the device should ~~stiff~~ still substantially retain its shape.

Replace the paragraph beginning on page 31, line 14, and ending on page 31, line 22, with:

However, the present molding element 230 can be used quite readily with a Flat woven piece of metal fabric, such as is illustrated in Figure 1B. In using such a fabric, a suitably sized and shaped piece of fabric is cut; in using the molding element 230 to produce a device 180 analogous to that shown in Figures 9A and 9B, for example, a generally disk-shaped piece of the metal fabric 10' can be used. The metal fabric is then placed between the two sections 232, 236 of the molding element and the sections are moved together to deform the fabric therebetween. After heat treatment, the fabric ~~an~~ can be removed and will retain substantially the same shape as it had when it was deformed between the two molding sections.

Replace the paragraph beginning on page 32, line 16, and ending on page 32, line 22, with:

In the embodiment of Figures 11A and 11B, the vascular trap 250 comprises a generally umbrella-shaped basket 270 carried adjacent a distal end of a guidewire 260. The guidewire in this embodiment includes a tapered distal section 262 with a spirally wound coil 264 extending along a distal length of the wire. Guidewires having such a distal end are conventional in the art. The basket

270 is positioned generally ~~distally~~ proximally of the coil 264, and is desirably attached to the guidewire proximally of the proximal end of the tapered section, as shown.

Replace the paragraph beginning on page 36, line 10, and ending on page 36, line 19, with:

In the embodiment of Figures 11, the proximal ends of the tethers 290 are attached to a metal strap 292 which is itself attached to the shaft of the guidewire 260. In the present embodiment, the tethers are not attached to the core wire 265 itself. Instead, the tethers are attached to the coil 266 of the guidewire. The tethers may be attached to the coil by any suitable means, such as by means of laser spot welding, soldering or brazing. The tethers 290 may be attached to the coil 266 at virtually any spot along the length of the coil. As illustrated in these drawings, for example, the tethers may be attached to the coil adjacent the coil's distal end. However, if so desired the tethers may be attached to the coil at a location ~~space~~ spaced more proximally from the basket 270.

Replace the paragraph beginning on page 36, line 29, and ending on page 37, line 6, with:

Figures 13-15 illustrate yet another alternative embodiment of a vascular trap in accordance with the present invention. This vascular trap 300 includes a basket 320 received over a guidewire 310. In most respects, the basket 320 is directly analogous to the basket 270 illustrated in Figures 11-12. The basket 320 includes a proximal band ~~322~~ 324 and a distal band ~~324~~ 322. As in the embodiment of Figures 12A and 12B, the distal band may be attached to the guidewire adjacent its distal end. If so desired, though, a structure such as is

shown in Figures 11, wherein the guidewire extends distally beyond the basket, could instead be used.

Replace the paragraph beginning on page 37, line 7, and ending on page 37, line 15, with:

As best seen in its collapsed state (shown in Figure ~~12A~~ 13), the basket includes a distal segment 325 and a proximal segment 326, with the distal end of the distal segment being attached to the distal band ~~324~~ 322 and the proximal end of the proximal segment being attached to the proximal band ~~322~~ 324. When the basket 320 is in the expanded configuration (shown in Figure ~~12B~~ 14), the proximal segment 326 is received within the distal segment 325, defining a proximal lip 328 at the proximal edge of the device. The wall of the basket thus formed also includes a cavity 329 for trapping solids entrained in a fluid, such as emboli in a patient's blood stream.

Replace the paragraph beginning on page 41, line 29, and ending on page 42, line 9, with:

Once the medical device is collapsed and inserted into the catheter, it may be urged along the lumen of the catheter toward the distal end of the catheter. This may be accomplished by using a guidewire or the like to abut against the device and urge it along the catheter. When the device begins to exit the distal end of the catheter, which is positioned adjacent the desired treatment site, it will tend to resiliently return substantially entirely to its preset expanded configuration. Superelastic alloys, such as nitinol, are particularly useful in this application because of their ability to readily return to a particular configuration after being elastically deformed to a great extent. Hence, simply urging the medical device out of the distal end of the catheter ~~tend~~ tends to properly deploy the device at the

treatment site.

Replace the paragraph beginning on page 42, line 20, and ending on page 42, line 30, with:

If the device is to be used to permanently occlude a channel in the patient's body, such as the devices 60 and 80 described above may be, one can simply retract the catheter and remove it from the patient's body. This will leave the medical device deployed in the patient's vascular system so that it may occlude the blood vessel or other channel in the patient's body. In some circumstances, the medical device may be attached to a delivery system in such a manner as to secure the device to the end of the delivery means, such as when the threaded clamp 90 shown in Figures 6 and 9 ~~are~~ is attached to a distal end of the delivery means, as explained above. Before removing the catheter in such a system, it may be necessary to detach the medical device from the delivery means before removing the catheter and the delivery means.

Replace the paragraph beginning on page 45, line 15, and ending on page 45, line 28, with:

The method of retracting the basket will depend on which embodiment of the vascular trap is used, namely whether or not the device includes a cover 340. The ~~device~~ devices 250 or 250' of Figures 11 or 12, respectively, do not include such a cover. However, they do include tethers 290 which extend proximally from the proximal lip 288 of the basket to an attachment to the guidewire. In either of these embodiments, a retrieval catheter can be introduced over the guidewire and urged distally toward the basket. As explained above in connection with Figures 11 and 12, this will tend to draw the tethers down toward the guidewire, effectively closing the proximal end of the basket 270. Once the basket is

sufficiently closed, such as when the proximal lip of the basket engages the distal tip of the retrieval catheter, the catheter and the vascular trap can be retracted together from the patient's body. By substantially closing the proximal end of the basket in such a fashion, any emboli which are captured in the basket when it is deployed can be retained within the basket until it is removed from the patient's body.